

# Ondansetron Kabi

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I being given Ondansetron Kabi?

Ondansetron Kabi contains the active ingredient ondansetron. Ondansetron Kabi is used to help stop nausea (feeling sick) and vomiting which can occur after medical treatments and operations.

For more information, see Section [1. Why am I being given Ondansetron Kabi?](#) in the full CMI.

### 2. What should I know before I am given Ondansetron Kabi?

Do not use if you have ever had an allergic reaction to Ondansetron Kabi or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given Ondansetron Kabi?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Ondansetron Kabi and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is Ondansetron Kabi given?

Your doctor will decide how much Ondansetron Kabi you should receive and for how long you should receive it.

More instructions can be found in Section [4. How is Ondansetron Kabi given?](#) in the full CMI.

### 5. What should I know after being given Ondansetron Kabi?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are receiving Ondansetron Kabi.</li><li>• Keep all of your doctor's appointments, so that your progress can be checked.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take any other medicines whether they require a prescription or not without first telling your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Ondansetron Kabi affects you.</li><li>• Ondansetron Kabi may cause dizziness or drowsiness in some people.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Ondansetron Kabi is stored by hospital staff in the pharmacy or in the ward.</li><li>• This medicine is kept below 30 °C and protected from light.</li></ul>

For more information, see Section [5. What should I know after being given Ondansetron Kabi?](#) in the full CMI.

### 6. Are there any side effects?

**Less serious side effects:** related to nervous system (headache), gastrointestinal (constipation, dry mouth, mild stomach cramps, diarrhoea), respiratory (hiccups), eye (prolonged upward deviation of the eyes), injection site (pain, itching, swelling, redness around the site of injection) and other (sensation of warmth or flushing). **Speak to your doctor if you have any of these less serious effects and they worry you.**

**Serious side effects:** related to heart (chest pain, tightness in chest, changes in your heart beat, severe dizziness/fainting), blood vessel (low blood pressure), nervous system (seizures), serotonin syndrome (confusion, fever, sweating, fast heart beat, agitation/confusion, involuntary or loss of muscle coordination or shaking, possible loss of consciousness), skin (severe skin reaction where the top layer of the skin detaches from the lower layers), allergic reaction (swelling of eyelids/face/lips/mouth/throat, wheezing or difficulty in swallowing/breathing, skin rash/lumps/hives) and other (blurred vision). **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Ondansetron Kabi

Active ingredient: Ondansetron (as hydrochloride dihydrate)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Ondansetron Kabi. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ondansetron Kabi.**

### Where to find information in this leaflet:

1. [Why am I being given Ondansetron Kabi?](#)
2. [What should I know before I am given Ondansetron Kabi?](#)
3. [What if I am taking other medicines?](#)
4. [How is Ondansetron Kabi given?](#)
5. [What should I know while receiving Ondansetron Kabi?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I being given Ondansetron Kabi?

Ondansetron Kabi contains the active ingredient **ondansetron**. Ondansetron Kabi belongs to a group of medicines called serotonin receptor-3 antagonists.

Ondansetron Kabi is used to help stop nausea (feeling sick) and vomiting which can occur after medical treatments and operations.

Your doctor may have prescribed Ondansetron Kabi for another reason. Ask your doctor if you have any question about why Ondansetron Kabi has been prescribed for you.

Ondansetron Kabi is not addictive.

## 2. What should I know before I am given Ondansetron Kabi?

### Warnings

#### Do not use Ondansetron Kabi if:

- you are allergic to ondansetron, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine. Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face/lips/tongue or other parts of the body, rash, itching or hives on the skin.
- you are taking apomorphine (a medicine used to treat Parkinson's disease).

#### Check with your doctor if you:

- have any other medical conditions
  - a heart condition related to changes in the rhythm or rate of your heart beat

- take any medicines for any other condition
- have allergies to any other medicines, foods, dyes or preservatives
- have had an allergic reaction with other medicines used to prevent nausea and vomiting; you may have an allergic reaction to Ondansetron Kabi as well
- have or used to have liver problems
- have severe constipation.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

**Check with your doctor if you are pregnant or intend to become pregnant.** Ondansetron Kabi is not recommended for use while you are pregnant.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.** Ondansetron Kabi is not recommended for use while you are breastfeeding.

## Serotonin syndrome

- Serotonin syndrome occurs when the level of serotonin gets too high.
- Symptoms may vary from mild (shivering, diarrhoea) to severe (muscle rigidity, fever, seizures). **Check with your doctor if you experience these symptoms while on Ondansetron Kabi treatment.**

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

### Some medicines may interfere with Ondansetron kabi and affect how it works.

- medicines used to treat conditions of abnormal heart beat
- certain medicines used to treat Parkinson's disease (apomorphine), since this may cause low blood pressure and loss of consciousness
- certain type of antidepressant medicines (known as SSRIs and SNRIs), since this may cause serotonin syndrome

- tramadol, since the pain-relieving effect thereof might be reduced.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ondansetron Kabi.**

#### 4. How is Ondansetron Kabi given?

##### How much is given

- Your doctor will decide how much Ondansetron Kabi you will receive and for how long you will receive it; this depends on your condition and other factors such as your weight.

##### When Ondansetron Kabi is given

- Ondansetron Kabi will be administered to you before starting with your chemotherapy or radiotherapy or at the start of, or after, your anaesthesia.

##### How Ondansetron Kabi is given to you

- Ondansetron Kabi will only be given to you by a doctor or a nurse
- Ondansetron Kabi will be injected into a muscle (intramuscular), or diluted with a suitable infusion before it is administered to you as a slow single dose injection/infusion into a vein (intravenous 'drip').

##### If you are given too much Ondansetron Kabi

Since Ondansetron Kabi is given to you in hospital by a doctor or a nurse, it is very unlikely that you will be given too large a dose.

However, if you think that you have received too much Ondansetron Kabi and you experience severe side effects, tell your doctor immediately.

Symptoms of an overdose may include the side effects listed below in the 'Side effects' section, but are usually of a more severe nature. Ask your doctor or pharmacist if you have any concerns.

#### 5. What should I know while receiving Ondansetron Kabi?

##### Things you should do

**Keep all of your doctor's appointments, so that your progress can be checked.**

**Call your doctor straight away if you:**

- become pregnant while being given Ondansetron Kabi.

Remind any doctor, dentist or pharmacist you visit that you are receiving Ondansetron Kabi.

##### Things you should not do

- Do not take any other medicines whether they require a prescription or not without first telling your doctor.

##### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Ondansetron Kabi affects you.**

Ondansetron Kabi may cause dizziness in some people.

##### Looking after your medicine

Ondansetron Kabi is stored by hospital staff in the pharmacy or in the ward.

This medicine is kept below 30 °C and protected from light.

##### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, hospital staff will take it to the pharmacy for safe disposal.

Do not use this medicine after the expiry date.

#### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

##### Less serious side effects

Less Serious side effects	What to do
<b>Nervous system-related:</b> <ul style="list-style-type: none"> <li>• headache</li> </ul> <b>Gastrointestinal-related:</b> <ul style="list-style-type: none"> <li>• constipation</li> <li>• dry mouth</li> <li>• mild stomach cramps</li> <li>• diarrhoea</li> </ul> <b>Respiratory system-related:</b> <ul style="list-style-type: none"> <li>• hiccups</li> </ul> <b>Eye-related:</b> <ul style="list-style-type: none"> <li>• prolonged involuntary upward deviation of the eyes</li> </ul> <b>Injection site-related:</b> <ul style="list-style-type: none"> <li>• pain, itching, swelling, redness around the site of injection</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Other:</b>	
<ul style="list-style-type: none"> <li>sensation of warmth or flushing</li> </ul>	

it is important to note that blood vessel blockage has also occurred in these illnesses and treatments when ondansetron injection has NOT been used. Discuss with your doctor if you have any concerns.

## Serious side effects

Serious side effects	What to do
<b>Heart-related:</b> <ul style="list-style-type: none"> <li>chest pain</li> <li>tightness in chest</li> <li>changes in your heart beat, e.g. beating faster or slower than normal, or if it beats irregularly or if it 'throbs'</li> <li>severe dizziness or fainting</li> </ul> <b>Blood vessel system-related:</b> <ul style="list-style-type: none"> <li>low blood pressure</li> </ul> <b>Nervous system-related:</b> <ul style="list-style-type: none"> <li>seizures</li> </ul> <b>Serotonin syndrome-related:</b> <ul style="list-style-type: none"> <li>confusion</li> <li>fever</li> <li>sweating</li> <li>fast heart beat</li> <li>agitation or confusion</li> <li>involuntary or loss of muscle coordination or shaking</li> <li>possible loss of consciousness</li> </ul> <b>Skin-related:</b> <ul style="list-style-type: none"> <li>severe skin reaction where the top layer of the skin detaches from the lower layers</li> </ul> <b>Allergic reaction-related:</b> <ul style="list-style-type: none"> <li>swelling of the eyelids, face, lips, mouth or throat</li> <li>wheezing, or difficulty in swallowing or breathing</li> <li>skin rash, skin lumps or hives</li> </ul> <b>Other:</b> <ul style="list-style-type: none"> <li>blurred vision</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects after being discharged from the hospital.</b></p>

**If your nausea (feeling sick) or vomiting does not go away, ask your doctor what to do.**

In certain illnesses and treatments where ondansetron has been used, blood vessel blockage has occurred. However,

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/safety/reporting-problems](http://www.tga.gov.au/safety/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Ondansetron Kabi contains

<b>Active ingredient (main ingredient)</b>	Ondansetron (as hydrochloride dihydrate)
<b>Other ingredients (inactive ingredients)</b>	Citric acid monohydrate Sodium citrate dihydrate Sodium chloride Water for injections

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Ondansetron Kabi looks like

#### Ondansetron Kabi injection ampoule 4 mg/2 mL:

2 mL clear, colourless, aqueous solution is supplied in clear 2 mL glass ampoules.

Pack size: 1, 5 or 10 ampoules per carton.

AUST R 191018

#### Ondansetron Kabi injection ampoule 8 mg/4 mL:

4 mL clear, colourless, aqueous solution is supplied in clear 5 mL glass ampoules.

Pack size: 1, 5 or 10 ampoules per carton.

AUST R 188775

### Who distributes Ondansetron Kabi

Fresenius Kabi Australia Pty Limited  
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